DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 9 2000

Mr. Dave Kolesar
Senior Vice President
RhiGene Inc.
455 State Street Suite 104
Des Plaines, Illinois 60016

Re: K000755
Trade Name: RhiGene MESACUP2 TEST - Sm
Regulatory Class: II
Product Code: LKP
Dated: April 24, 2000
Received: April 28, 2000

Dear Mr. Kolesar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000755

Device Name: RhiGene MESACUP2 TEST - Sm

Indications for Use:

Sm antibody is an ENA antibody named after "Smith", a patient who suffered from Systemic Lupus Erythematosus (SLE). Sm antibody is frequently found with RNP antibody. It is detected in 10-30% of SLE patients. At high levels, Sm antibody is indicative of SLE and is rarely detected in other diseases. It has been adopted as a marker for diagnosis of SLE by the American Rheumatism Association (ARA). Anti-Sm is observed at a high titer in the active period of SLE and at a low titer in the nonactive period. Raynaud's phenomena and nephropathy are reported more frequently in SLE patients testing positive for anti-Sm.

The RhiGene MESACUP2 TEST - Sm is a semi-quantitative enzyme-linked immunosorbent assay for the detection of antibodies to Sm in human serum. The RhiGene MESACUP2 TEST- Sm is intended for *in vitro* diagnostic use mainly as an aid in the diagnosis of Systemic Lupus Erythematosis.

The RhiGene MESACUP2 TEST - Sm uses native purified proteins of Sm-D for the solid phase antigen. Therefore, the test show increased specificity for detection of specific autoantibodies present in the sera of patients with Systemic Lupus Erythematosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000755

Prescription Use ✓ **OR** **Over-The-Counter Use**__
(Per 21 CFR 801.109)

(Optional Format 1-2-96)